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# One Hundred Fifth Congress of the United States of America

## AT THE FIRST SESSION

*Begun and held at the City of Washington on Tuesday, the seventh day of January, one thousand nine hundred and ninety-seven*

# An Act

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the "Food and Drug Administration Modernization Act of 1997".

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

"(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.".

(b) ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

"(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.".

**SEC. 125. INSULIN AND ANTIBIOTICS.**

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—

(1) AMENDMENT.—Section 506 (21 U.S.C. 356), as in effect before the date of the enactment of this Act, is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 301(j) (21 U.S.C. 331(j)) is amended by striking "506, 507,".

(B) Subsection (k) of section 502 (21 U.S.C. 352) is repealed.

(C) Sections 301(i)(1), 510(j)(1)(A), and 510(j)(1)(D) (21 U.S.C. 331(i)(1), 360(j)(1)(A), 360(j)(1)(D)) are each amended by striking ", 506, 507,".

(D) Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by inserting after "503(b)" the following: "or composed wholly or partly of insulin".

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting "or" at the end of subparagraph (B), by striking "; or" at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

(b) CERTIFICATION OF ANTIBIOTICS.—

(1) AMENDMENT.—Section 507 (21 U.S.C. 357) is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out "or 507", section 201(dd) (21 U.S.C. 321(dd)) is amended by striking "507,", and section 201(ff)(3)(A) (21 U.S.C. 321(ff)(3)(A)) is amended by striking ", certified as an antibiotic under section 507,".

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking "507(d) or (g),".

(C) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking "or 507".

(D) Section 502 (21 U.S.C. 352) is amended by striking subsection (l).

(E) Section 520(l) (21 U.S.C. 360j(l)) is amended by striking paragraph (4) and by striking "or Antibiotic Drugs" in the subsection heading.

(F) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting "or" at the end of paragraph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(G) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking ", certification of such drug for such disease or condition under section 507,".

(H) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking "the submission of an application for certification of the drug under section 507,", by inserting "or" at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(I) Section 526(b) (21 U.S.C. 360bb(b)) is amended—

(i) in paragraph (1), by striking ", a certificate was issued for the drug under section 507,"; and

(ii) in paragraph (2) by striking ", a certificate has not been issued for the drug under section 507," and by striking ", approval of an application for certification under section 507,".

(J) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting "or" at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking ", issue another certification under section 507,".

(K) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking ", if a certification is issued under section 507 for such a drug,", ", of the issuance of the certification under section 507,", ", issue another certification under section 507,", ", of such certification,", ", of the certification,", and ", issuance of other certifications,".

(L) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking ", section 507 (d) or (g),".

(M) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting "or" at the end of subparagraph (B), by striking subparagraph (C), and by redesignating subparagraph (D) as subparagraph (C).

(N) Subparagraphs (A)(ii) and (B) of sections 5(b)(1) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking "or 507".

(O) Section 45C(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking "or 507".

(P) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking "507," each place it occurs.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended by adding at the end the following:

"(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).".

(d) TRANSITION.—

(1) IN GENERAL.—An application that was approved by the Secretary of Health and Human Services before the date of the enactment of this Act for the marketing of an antibiotic drug under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as in effect on the day before the date of the enactment of this Act, shall, on and after such date of enactment, be considered to be an application that was submitted and filed under section 505(b) of such Act (21 U.S.C. 355(b)) and approved for safety and effectiveness under section

505(c) of such Act (21 U.S.C. 355(c)), except that if such application for marketing was in the form of an abbreviated application, the application shall be considered to have been filed and approved under section 505(j) of such Act (21 U.S.C. 355(j)).

(2) EXCEPTION.—The following subsections of section 505 (21 U.S.C. 355) shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of such Act (21 U.S.C. 357) before the date of the enactment of this Act:

(A)(i) Subsections (c)(2), (d)(6), (e)(4), (j)(2)(A)(vii), (j)(2)(A)(viii), (j)(2)(B), (j)(4)(B), and (j)(4)(D); and

(ii) The third and fourth sentences of subsection (b)(1) (regarding the filing and publication of patent information); and

(B) Subsections (b)(2)(A), (b)(2)(B), (b)(3), and (c)(3) if the investigations relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(3) PUBLICATION.—For purposes of this section, the Secretary is authorized to make available to the public the established name of each antibiotic drug that was the subject of any application for marketing received by the Secretary for Health and Human Services under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) before the date of enactment of this Act.

(e) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 121(a)(1), is further amended by adding at the end the following:

"(jj) The term 'antibiotic drug' means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.".

**SEC. 126. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.**

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

"(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

"(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).".

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and